GOVERNMENT OF INDIA
SCIENCE AND TECHNOLOGY
LOK SABHA

UNSTARRED QUESTION NO:3165
ANSWERED ON:10.12.2002
ANTI-FERTILITY VACCINE FOR WOMEN
MANEKA SANJAY GANDHI

Will the Minister of SCIENCE AND TECHNOLOGY be pleased to state:

(a) the number of women participated in the Phase 1 & 2 human clinical trials initiated as part of the research on the anti-fertility vaccine for women (Anti-LCC);

(b) the nature of follow up action taken on the women who have undergone Phase 1 &2 clinical trials of this anti-fertility vaccine;

(c) whether such women have been tested for long term side effects such as auto immune disorders of the vaccine by anyone other than the researchers concerned in the manufacture of the vaccine;

(d) if so, the details thereof;

(e) the number of safe and reversible contraceptive vaccines developed under this project;

(f) whether these are available in the market today;

(g) if so, the name of the company marketing these vaccines; and

(h) the money invested in the project so far and the total expenditure incurred thereon?

Answer

MINISTER OF STATE FOR SCIENCE AND TECHNOLOGY(SHRI BACHI SINGH RAWAT)

(a): The Phase-I clinical trial of B hCG vaccine was conducted on140 volunteers while 110 volunteers participated in Phase-II efficacy trials.

(b): The follow up was conducted to establish the reversibility of antibodies response, and to assess immunological safety of the vaccine.

(c)&(d): Long term follow up has been done to assess the side effects by medical experts of a reputed Institute other than the researchers who developed this vaccine. The data available so far indicated no adverse consequences attributable to the B hCG vaccination.

(e): Beta hCG vaccine has been developed as a candidate vaccine and has undergone Phase-I and Phase-II clinical trials. The large Phase-III clinical trials have not been conducted since the analysis of the data generated under Phase-I andII suggested basic research to be undertaken to improve formulation. Thus, the present B hCG formulation is not ready for human use at this stage.

(f)&(g): The product is not available in the market.

(h): An expenditure of about Rs.9.64 crores has been made in the development and conduction of Phase-I and Phase-II clinical trials for B hCG at National Institute of Immunology and other Institutions.